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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,272	10/29/2001	Bobby Neal Glover	PU3126US2	8388

23347 7590 08/11/2003

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EXAMINER

CRANE, LAWRENCE E

ART UNIT PAPER NUMBER

1623

DATE MAILED: 08/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/007,272	Applicant(s) Glov r t al.	
	Examiner L. E. Crane	Group Art Unit 1623	

- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

Status

- ☒ Responsive to communication(s) filed on **-03/06/03 (Response)-**.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claims **--11, 14 and 16-21--** are pending in the application. Claims **-[]-** have been cancelled.

Of the above claim(s) **--[]--** is/are withdrawn from consideration.

- ☐ Claim(s) **--[]--** is/are allowed.
- ☒ Claims **--11, 14 and 16-21--** are rejected.
- ☐ Claim(s) **--[]--** is/are objected to.
- ☐ Claim(s) **--[]--** are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The proposed drawings, filed on **-10/29/01-** are ☒ approved ☐ disapproved.
- ☐ The drawing(s) filed on **-[]-** is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119(a)-(d)

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☒ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-[]-**.
- ☒ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: **-[]-**.

Attachment(s)

- | | |
|--|---|
| <input type="checkbox"/> Information Disclosure Statement(s), PTO-1449, Paper No(s). -[]- | <input type="checkbox"/> Interview Summary, PTO-413 |
| <input type="checkbox"/> Notice of Reference(s) Cited, PTO-892 | <input type="checkbox"/> Notice of Informal Patent Application, PTO-152 |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review, PTO-948 | <input type="checkbox"/> Other: -[]- |

U.S. Patent Trademark Office

Office Action Summary

PTO-326 (Rev. 06/19/01)

S. N. 10/007,272

Paper No. **09**

Copy for **FILE** ☐ APPLICANT

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No claims have been cancelled, no claims have been amended, and no new claims have been added as per the response filed March 6, 2003. No additional Information Disclosure Statements (IDSs) have been received. A Terminal Disclaimer has been received, reviewed, found
5 acceptable, and made of record.

Claims 11, 14 and 16-21 remain in the case.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

10 "A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

15 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(c) the invention was described in

20 (1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

25 (2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

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Claims 11, 14 and 16-21 are rejected under 35 U.S.C. §102(e) as being anticipated by Chamberlain et al. '832 (PTO-1449 ref. A K).

Applicant is referred to claims 20-23 (pharmaceutical compositions) and claims 26-28 (methods of treating herpes viral infections) of the '832 reference wherein the instant claimed subject matter has been anticipated. The particular crystal structure, mixture of crystal structures, or absence of crystal structure of the active ingredient is deemed to be irrelevant to the pharmaceutical efficacy thereof because the pharmaceutical activity of the active ingredient is a function of the molecular structure(s) adsorbed by the cells contacted by the composition and/or the crystal structure is destroyed by dissolution of the crystalline solid by the pharmaceutically acceptable carrier.

Applicant's arguments filed March 6, 2003 have been fully considered but they are not deemed to be persuasive.

Applicant has argued that the instant claims do not anticipate the subject matter of the cited reference because they include limitations not found in the prior art and therefore are not anticipated. Examiner respectfully disagrees.

The treatment of any herpes simplex viral disease condition does not occur via contact of any one crystalline form of the solid compound specified herein, but does occur at the molecular level following complete dissolution of the active ingredient either by the pharmaceutical carrier or by one of the human circulatory fluids, or a combination thereof. Therefore, the biological activity of the active ingredient is not be a function of the particular orientation of molecules in a particular crystalline form. For this reason examiner concludes that

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the limitations applicant alleges are critical to the patentability of the instant claims over the cited prior art are in fact not critical, and moreover cannot be permitted to distinguish the instant claims over the prior art.

5 As to the technical issue of whether the instant claims are anticipated, examiner argues that said claims are anticipated because the biological activity of the pharmaceutical compositions being claimed, and the biological activity relied upon by the methods of treatment of herpes viral infections being claimed, are both identical with the activity
10 relied upon by the prior art disclosure. Therefore, while the instant claims are not identical with the prior art disclosure, they are effectively anticipated because the alleged basis for distinction over the prior art, the specific crystalline form of the active ingredient, has no effect
15 whatsoever on the inherent biological activity of the molecules of the active ingredient. Examiner also notes that applicant had admitted that this is true: see applicant's response of March 6, 2003 at page 4, paragraph 2, first sentence. And examiner notes that applicant has not alleged, or provided any factual disclosure supporting, any unexpected technical advantage associated with one or more of the crystalline forms
20 specified in any single pharmaceutical composition or method of treatment claim.

For these reasons the instant grounds of rejection have been maintained.

25 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

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A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at (703)-308-4624.

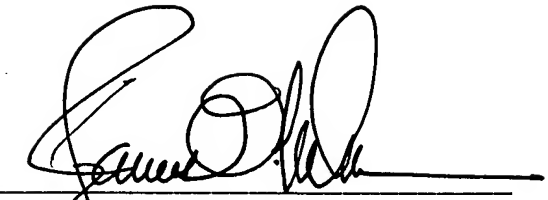
Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

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08/01/03



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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